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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,201	09/24/2001	Vishva M. Dixit	PF335D2	6537

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HUMAN GENOME SCIENCES INC
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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,201

Applicant(s)

DIXIT ET AL.

Examiner

Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 12, 14, 15 and 17-74 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10, 12, 14, 15 and 17-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-26, 30-33, 35-39, 41-47, 51-54, 57-61, and 63 is/are allowed.
- 6) ☒ Claim(s) 27-29, 34, 40, 48-50, 55, 56, 62 and 64-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 10, 12, 14-15, 17-74 are pending.
2. Claims 1, 10, 12, 14-15, and 17-20 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
3. The request that claims 33-34 and 54-56 be rejoined with the allowed antibodies and examined for patentability is acknowledged. Claims 33-34 and 54-56 are hereby rejoined with claims 21-32, 35-53, and 57-74.
4. Claims 21-74 are being acted upon in this Office Action.
5. The following new ground of rejection is necessitated by the amendment filed 2/19/04.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 27, 48, 66, and 68-74 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

“An isolated antibody...amino acid residues **about 10 to about 20** of SEQ ID NO: 1, ...amino acid residues **about 40 to about 50** of SEQ ID NO: 1...amino acid residues **about 70 to about 90** of SEQ ID NO: 1, ...amino acid residues **about 100 to about 113** of SEQ ID NO: 1 ” in Claim 68 represents a departure from the specification and the claims as originally filed.

Applicants' arguments filed 2/19/04 have been fully considered but are not found persuasive.

Applicants' position is that (1) page 12, line 7 of the election and preliminary amendment filed 8/4/03, the particular amino acid sequences of claim 68 are support in page 27, lines 14-24.

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However, currently amended claim 68 recites An isolated antibody or fragment thereof, wherein the antibody has been obtained from an animal that has been immunized with a protein consisting of an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of amino acid residues about 10 to about 20 of

SEQ ID NO:1;

(b) the amino acid sequence of amino acid residues about 40 to about 50 of

SEQ ID NO: 1.,

(c) the amino acid sequence of amino acid residues about 70 to about 90 of

SEQ ID NO:1; and

(d) the amino acid sequence of amino acid residues about 100 to about 113

of SEQ ID NO:1; wherein said antibody or fragment thereof specifically binds to said amino acid sequence. The specification or the claims as originally file do not support said phrase.

“... the antibody or fragment thereof is *human*” in claim 27 represents a departure from the specification and the claims as originally filed. Applicant has not pointed out the support for said phrase.

“... the antibody or fragment thereof is *human*” in claim 48 represents a departure from the specification and the claims as originally filed. Applicant has not pointed out the support for said phrase.

“... the antibody or fragment thereof is *human*” in claim 66 represents a departure from the specification and the claims as originally filed. Applicant has not pointed out the support for said phrase.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 27-29, 34, 40, 48-50, 55-56, 62 and 64-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The “wherein the antibody or fragment thereof is *human*” in claims 27, 48, and 66 is ambiguous and indefinite because the antibody or fragment thereof is NOT human. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

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The antibody that binds to ICE-LAP 6 protein in claim 64 “is encoded by a polynucleotide encoding amino acids 1 to 416 of SEQ ID NO: 1 operably associated with a regulatory sequence that controls the expression of said polynucleotide is ambiguous and indefinite because if the antibody or fragment thereof binds to a protein consisting of 1 to 416 of SEQ ID NO: 1, then the claim should recite that protein. As written, it is not clear LAP6 protein is amino acids 1 to 416 of SEQ ID NO: 1.

The “or a fragment of a polyclonal antibody” in claims, 28, 34, 49, and 55 is ambiguous because it is not clear if is the binding fragment or the Fc fragment of the antibody is being claimed. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.

The “or a fragment of a monoclonal antibody” in claims, 29, 40, 50, 56, 62 and 65 is ambiguous because it is not clear if is the binding fragment or the Fc fragment of the antibody is being claimed. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.


10. Claims 21-26, 30-33, 35-39, 41-47, 51-54, 57-61, and 63 are allowed.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
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May 3, 2004


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